

HL7 SPL Working Group Process Communication Forum Telecon
Wednesday, January 11, 2012

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov

SPL technical questions? Send to spl@fda.hhs.gov

UNII or SRS questions? Send to fda-srs@fda.hhs.gov

As of January 11, 2012: DailyMed has over 32,900 SPL loaders.

Minutes:

Agenda:

- New validation rule related to including product NDC code for each manufacturing establishment.
 - Implementation timing: Feb 1, 2012
 - We will be collecting your questions -- so that we can clarify the process prior to the implementation date.
- Other questions from the meeting and walk-ins

[There are a lot of details that will also be included in the ER/DL Subteam meeting minutes, expected to be released in the next week or so]

A validation rule will be implemented that will require establishments to reference the product NDCs. Each product NDC must be linked to at least one establishment. This will allow a way to match-up the specific establishment to a specific product/NDC.

Each product in the SPL must be linked to at least one establishment in the establishment section.

- This rule has been in the validation rules since 2010; it will be enforced starting February 1, 2012.
- Implementation is particular to CDER-regulated products. CBER and Vet products are not currently required to provide this linkage.
- Sponsors should check with their SPL software vendors to make sure that they have this functionality in the tool
- Enter NDCs to the product level – not to the pack size level. The stylesheet does NOT allow 10 digit NDCs (i.e., to the pack level).
- This does not apply to all SPL – it is dependent on marketing category, document type etc. **Currently, this validation rule applies to CDER products only.** The goal of this rule is to establish a clear supply chain for each product.
- There has been discussion about whether this validation rule will eventually change to an association down to the pack level. Also about which business operations are impacted.
- Internal discussions ongoing at FDA around listing inner packs separately.
- Questions are being collected and sent back to DRLS.

Duplicate file deletion:

Process for deleting duplicate files – new option possibly

In response to the request to automate the process of archiving SPL R3 or duplicate SPL R4 documents on DailyMed sans the requirement to add the marketing status and marketing start and end dates (SPL R3) or the update of the marketing status to "completed" and entry of a marketing end date (**duplicate** SPL R4) and to honor industry requests (received from 2005 - 2009) regarding drug companies' opposition to the FDA's system altering the data elements in drug companies' SPL files, here is the solution which will afford an opportunity for SPL document authors to archive on DailyMed SPL R3 documents which need to be "retired" and instances of SPL R4 documents, which due to the combination of package inserts, need to be archived on DailyMed.

Send questions or concerns to spl@fda.hhs.gov by January 20, 2012

The Technical Team will discuss these at the January 30, 2012.

Target implementation: February 2012 (once concerns are addressed).

FYI:

- **The section name for Drug Product Listing is changing to SPL Listing Data Elements.** SPL can use either name between now and July 2012. After July 1, only the DPL section title will be allowed.
- DUNS portal: Jean confirmed with D&B that they are still working on the portal but have been delayed. They will get back to us next week with new timing.
- New training manual expected in the near future for Xforms.

Schedule for the 2012 SPL training sessions:

Webinars, Telephone call-in sessions:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>.

Note on Telephone call-in sessions: These don't restart for 2012 until January 23.

Next scheduled teleconference: January 25, 2012